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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/950,041	09/10/2001	Gerard T. Hardiman	DX0724XX1	2187

28008 7590 04/11/2003

DNAX RESEARCH, INC.  
LEGAL DEPARTMENT  
901 CALIFORNIA AVENUE  
PALO ALTO, CA 94304

EXAMINER

HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
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1647

DATE MAILED: 04/11/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/950,041

Applicant(s)

HARDIMAN ET AL.

Examiner

Fozia M Hamud

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on 06 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) 1-22 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restriction*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1 and 8, drawn to an isolated polypeptide comprising a specific amino acid sequence as set forth below, classified in class 530, subclass 350.
  - II. Claims 2-3, drawn to drawn to an isolated nucleic acid molecule, classified in class 536, subclass 23.5.
  - III. Claims 4-7, 9-14, a binding compound which specifically binds to a polypeptide, classified in class 530, subclass 389.1.
  - IV. Claims 15-16, drawn to a method of treating a patient having sepsis by administering a compound that binds to SEQ ID NO:8, classified in class 424, subclass 144.1.
  - V. Claims 17-18, drawn to a method of treating a patient having sepsis by administering a compound that binds to SEQ ID NO:26, classified in class 424, subclass 144.1.
  - VI. Claims 19-20, drawn to a method of treating a patient by administering a compound that binds to SEQ ID NO: 22, classified in class 424, subclass 144.1.
  - VII. Claims 21-22, drawn to a method of treating a patient having sepsis by administering a compound that binds to SEQ ID NO: 41, classified in class 424, subclass 144.1.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are independent and distinct, each from the other, because they are products which possess characteristic differences in structure and function and each has an independent utility, that is distinct for each invention which cannot be exchanged. The nucleic acid of Group II can be used to make a hybridization probe or can be used in gene therapy as well as in the production of the protein of interest. The protein of Group I can be used other than to make the antibody of Group III, such as used as a probe, or used therapeutically or diagnostically (e.g. in screening). Although

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the antibody of Group III can be used to obtain the nucleic acid of Group II, it can also be used in diagnostics (e.g. as a probe in immunoassays, or in immunochromatography) or it may be used therapeutically.

Inventions I, II and IV-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together, or they have different modes of operation, or they have different functions, or they have different effects. (MPEP § 806.04, MPEP § 808.01). In the instant case the methods of Groups IV-VII neither use nor produce the polypeptide or the nucleic acid Groups I and II.

Inventions III and IV-VII are related as product and processes of use. However, the inventions are distinct because the binding compound of Group III as claimed can be used in materially different methods, such as it can be used purification purposes.

Inventions IV-VII are independent and distinct, each from the other, because the methods are practiced with materially different process steps for materially different purposes and each method requires a non-coextensive search because of different goals. The methods are distinct because each assay is performed for divergent purposes.

Having shown that these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter as defined by MPEP § 808.02, the Examiner has prima facie shown a serious burden of search (see MPEP § 803). Therefore, an initial requirement of restriction for examination purposes as indicated is proper.

#### **Additional Restriction Requirement**

2. The claims of Group I-III, are drawn to a multitude of polypeptides, nucleic acid molecules encoding said polypeptide and binding compounds that specifically bind to said polypeptides, (polypeptides of SEQ ID Nos:6, 8, 10, 12, 14, 16, 20, 22, 24, 26, 28, 30, 32, 34, 37, 41, or 45). This constitutes a recitation of an implied, mis-joined Markush group that contain multiple, independent and distinct inventions. Each of the nucleic acids are independent and distinct because no common structural or functional properties are shared. Accordingly, these claims are subject to restriction under 35 U.S.C. 121.

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In the event that Applicant elects any of the inventions of Groups I-III, Applicant is additionally required to elect a single amino acid sequence. This requirement is not to be considered as a requirement of an election of species, since each of the compounds recited in alternative from is not a member of a single genus of invention, but constitutes an independent and patentably distinct invention.

3. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).


***Advisory Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia M Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Monday, Wednesday-Thursday, 6:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (703) 308-4623. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4227 for regular communications and (703) 308-0294 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Fozia Hamud  
Art Unit 1647  
April 8, 2003

  
GARY KUNZ  
SUPERVISORY PATENT EXAMINER  
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